Proposal for regulation amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP)

Topic: Multi-constituent classification rules

Amendment 1
Proposal for Regulation
Recital 2

Commission Proposal	Proposal for amendment
(2) From a toxicological point of view, substances with ~~more than one~~ constituent ~~('multiconstituent substances')~~ are no different from mixtures composed of two or more substances. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, aimed to limit animal testing, data on ~~multiconstituent~~ substances ~~is to be generated under the same conditions as data on any other substance~~, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, ~~multi-constituent~~ substances should be evaluated and classified following the same classification rules as mixtures, unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those ~~multi-constituent~~ substances.	(2) From a toxicological point of view, substances with constituent***s* (*as individual constituent, identified impurity or an additive) for which the information is available for this constituent*** are no different from mixtures composed of two or more substances. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, aimed to limit animal testing, data ***is to be generated*** on substances, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, substances should be evaluated and classified following the same classification rules as mixtures, unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those substances.
Justification Both REACH and CLP apply the same definition of a substance, which is coherent. However, the new CLP proposal seeks to introduce a new definition for multi-constituent substances for the purpose of clarifying classification rules for substances that contain impurities, additives or individual constituents above certain concentration limit. **This new definition in CLP is both confusing and unnecessary as it is at odds with how multi-constituent substances have been identified under REACH.** The classification rules can be clarified without introducing a new definition for multi-constituent substances.	

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Amendment 2

Proposal for Regulation
Recital 3

Commission Proposal	Proposal for amendment
(3) It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a ~~multi-constituent~~ substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the ~~multi-constituent~~ substance should therefore normally be used as the basis for hazard identification of those ~~multi-constituent~~ substances or mixtures. However, in certain cases, data on those ~~multi-constituent~~ substances themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on ~~multiconstituent~~ substances are used in those cases.	(3) It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the substance should therefore normally be used as the basis for hazard identification of those substances or mixtures. However, in certain cases, data on those substances ***or mixtures*** themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents ***or individual substances in the mixture***. Therefore, it is appropriate that data on substances ***or mixtures*** are used in those cases.

Justification

Both REACH and CLP apply the same definition of a substance, which is coherent. However, the new CLP proposal seeks to introduce a new definition for multi-constituent substances for the purpose of clarifying classification rules for substances that contain impurities, additives or individual constituents above certain concentration limit. **This new definition in CLP is both confusing and unnecessary as it is at odds with how multi-constituent substances have been identified under REACH.** The classification rules can be clarified without introducing a new definition for multi-constituent substances.

What is important is to clarify on a sound scientific basis when data on individual constituents (impurities, additives or constituents) or substance prevail vs when data generated on the 'whole substance' or 'mixture' can be used, and the CLP revision can do this without a new definition.

Amendment 3

Proposal for Regulation
Article 1- paragraph 2 – point 7a
Regulation 1272/2008
Article 2 – paragraph 7a (new)

Commission Proposal	Proposal for amendment
~~Article 2 (7a). 'multi-constituent substance' means a substance that contains more than one constituent.~~	delete
Justification Both REACH and CLP apply the same definition of a substance, which is coherent. However, the new CLP proposal seeks to introduce a new definition for multi-constituent substances for the purpose of clarifying classification rules for substances that contain impurities, additives or individual constituents above certain concentration limit. **This new definition in CLP is both confusing and unnecessary as it is at odds with how multi-constituent substances have been identified under REACH.** The classification rules can be clarified without introducing a new definition for multi-constituent substances.	

Amendment 4

Proposal for Regulation
Article 1- paragraph 4
Regulation 1272/2008
Article 5 – paragraph 3a (new)

Commission Proposal	Proposal for amendment
'3. A ~~multi-constituent~~ substance containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision. For the evaluation of ~~multi-constituent~~ substances pursuant to Chapter 2 in relation to the 'germ cell	3. A substance containing at least one constituent ***above the applicable concentration limit,*** in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision.

mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance. Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met: (a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine disrupting properties for human health or the environment; (b) the information supports the conclusions based on the relevant available information on the constituents in the substance. Relevant available information on the ~~multi-constituent~~ substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance. For the evaluation of ~~multi-constituent~~ substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance. Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:	For the evaluation of substances pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance. Relevant available information on the substance itself shall be taken into account where one of the following conditions are met: (a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine disrupting properties for human health or the environment; (b) the information supports the conclusions based on the relevant available information on the constituents in the substance. Relevant available information on the substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance. For the evaluation of substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance. Relevant available information on the substance itself shall be taken into account where one of the following conditions are met:

(a) the information demonstrates biodegradation, persistence, mobility and bioaccumulation properties. (b) the information supports the conclusions based on the relevant available information on the constituents in the substance. Relevant available information on the ~~multi-constituent~~ substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance.	(a) the information demonstrates biodegradation, persistence, mobility and bioaccumulation properties. (b) the information supports the conclusions based on the relevant available information on the constituents in the substance. Relevant available information on the substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance.
Justification Both REACH and CLP apply the same definition of a substance, which is coherent. However, the new CLP proposal seeks to introduce a new definition for multi-constituent substances for the purpose of clarifying classification rules for substances that contain impurities, additives or individual constituents above certain concentration limit. **This new definition in CLP is both confusing and unnecessary as it is at odds with how multi-constituent substances have been identified under REACH.** The classification rules can be clarified without introducing a new definition for multi-constituent substances. It is important to specify that the constituent, impurity or additive needs to be present in the substance above a given concentration limit, either generic or specific. This is the practice today and it should be added to this section which clarifies existing classification rules.	

Topic: CLH, Grouping

Amendment 1

Proposal for Regulation
Recital 18

Commission Proposal	Proposal for amendment
18. Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity allows for similar classification of all substances in the group. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation	18. Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity ***based on scientific justification (taking into account all available data on physico-chemical, ecotoxicological and toxicological properties as specified in REACH Annex XI (1.5)) using a weight of evidence approach,*** allows for similar

of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group.	classification of all substances in the group. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group.
Justification To speed up harmonised classification the Commission seeks to move away from a substance-by-substance approach and proposes to classify groups of substances based on 'similar classification'. **Structurally similar substances can have different behaviour and effects**. Therefore, the assessment of 'similarity' must be based on **a review of all available data** on the substances' physico-chemical, ecotoxicological and toxicological properties as already done under REACH (Annex XI, part 1.5 on grouping of substances and read-across approach). This review must be in line with well-established scientific practices and include a **Weight of Evidence** assessment across all relevant criteria for the hazard in question. Such an approach will help avoid over-classifying and over-regulating substances based on 'presumed' adverse effects.	

Amendment 2

Regulation 1272/2008
Article 37 – paragraph 4

Commission Proposal	Proposal for amendment
	4. The Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 shall ***check if the submitted proposal conforms with Annex VI Parts 1 and 2. The Committee for Risk Assessment of the Agency shall*** adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment ***taking into account the complexity of the proposal***. ***The Agency shall provide further guidance on how the harmonised classification proposal for group(s) of substances is to be developed, taking into account the complexity of the proposal.*** The Agency shall forward this opinion and any comments to the Commission.
Justification	

To ensure all CLH dossier submitters (e.g., Member States, Industry and – new proposal of the CLP revision – the European Commission) apply the same scientific principles to justify similar classification, **there is a need for a formal quality check mechanism, i.e. a conformity check (as applied according to REACH Art 64 (3) for Authorisation and Art 69 (4) for Restriction processes), performed by ECHA Committees and for an ECHA guidance that clarifies the scientific basis from which a harmonised classification for a group of substances can be derived**.

Introduction of new hazard classes under CLP will increase the workload of authorities, industry and ECHA's committees, in particular RAC. Therefore, **sufficient time should be given to allow for a thorough examination of each CLH dossier (including the e**xtended **possibility to comment for complex dossiers)**, ensuring harmonised classifications are assigned where justified based on a comprehensive review of the weight of scientific evidence.

Amendment 3

Regulation 1272/2008
Annex VI Part 2

Commission Proposal	Proposal for amendment
	PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling. The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 shall be used for the methodology and format of any dossier. For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier. A dossier for harmonised classification and labelling shall contain the following: — Proposal The proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed.

	— Justification for the proposed harmonised classification and labelling A comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006. ***— Justification for the proposed grouping of substances subject to harmonised classification and labelling*** ***Where a harmonised classification and labelling proposal is made for group(s) of substances, the dossier shall include scientific justification (based on assessment of available data on physico-chemical, ecotoxicological and toxicological properties as specified in REACH Annex XI (1.5)) using a weight of evidence approach, for the grouping of substances and for applying a similar classification.*** — Justification for other effects at Community level For other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC.
Justification **To speed up harmonised classification the Commission seeks to move away from a substance-by-substance approach and proposes to classify groups of substances based on 'similar classification'** . Structurally similar substances can have different behaviour and effects. Therefore, the assessment of 'similarity' must be based on **a review of all available data** on the substances' physico-chemical, ecotoxicological and toxicological properties as already done under REACH and included in the harmonised classification and labelling proposal for group of substances. This review must include a **Weight of Evidence** assessment across all relevant criteria for the hazard in question. This evidence together with the assessment of similarity need to be **transparently documented in the harmonised classification dossier.**	

Topic: formatting rules for labels

Amendment 1

Proposal for Regulation
Annex I – Part I – Section 1.2.1.4 – Table 1.3
Regulation 1272/2008
Annex I – Part I – Section 1.2.1.4 – Table 1.3

Commission proposal

'1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:

Table 1.3

Minimum dimensions of labels, pictograms and font size

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)	~~Minimum font size~~
Not exceeding 3 litres:	If possible, at least 52x74	Not smaller than 10x10 If possible, at least 16x16	~~8pt~~
Greater than 3 litres but not exceeding 50 litres:	At least 74x105	At least 23x23	~~12pt~~
Greater than 50 litres but not exceeding 500 litres:	At least 105x148	At least 32x32	~~16pt~~
Greater than 500 litres:	At least 148x210	At least 46x46	~~20pt';~~

~~(3) the following Section 1.2.1.5. is added:~~

~~'1.2.1.5. The text on the label shall have the following characteristics:~~

~~(a) the background of the label shall be white;~~

~~(b) the distance between two lines shall be equal or above 120 % of the font size;~~

~~(c) a single font shall be used that is easily legible and without serifs;~~

~~(d) the letter spacing shall be appropriate for the selected font to be comfortably legible.~~

~~For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.'~~

Proposal for amendment

'1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:

Table 1.3

Minimum dimensions of labels, pictograms and font size

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)
Not exceeding 3 litres:	If possible, at least 52x74	Not smaller than 10x10 If possible, at least 16x16
Greater than 3 litres but not exceeding 50 litres:	At least 74x105	At least 23x23
Greater than 50 litres but not exceeding 500 litres:	At least 105x148	At least 32x32
Greater than 500 litres:	At least 148x210	At least 46x46

Justification
While the new provisions allowing the use of fold-out labels are welcomed, they are not always practical for e.g., small items (below <10ml). The new rules for formatting labels are too stringent and too specific, particularly those prescribing a minimum font size and spacing requirements. A slight increase in font size would increase legibility, but the proposed increase is unnecessary and impractical: it would make current label sizes unusable for the majority of products and would reduce the number of languages that can be placed on one label and thus, considerably limit flexibility. In addition, companies would need new or updated software's to manage those requirements. Specific formatting rules should be kept in the guidance document, and current rules in CLP regulation should remain.

Topic: Updating labels

Amendment 1

Proposal for Regulation
Recital 10

Commission Proposal	Proposal for amendment
To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/14354.	To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/14354.
~~Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25,~~ ~~t~~he deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set ~~at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification~~	***T***he deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the

~~in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain~~ at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).	date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
Justification The new CLP Regulation proposal requires labels to be updated within 6 months in case a new hazard class or a more severe classification needs to be assigned to a substance or a mixture, or when new supplemental information on the label is required. This timeline is too short, in particular for complex value chains that involve several mixture formulators downstream, and inconsistent with current practices which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages. Consistent with current rules, we recommend that **18 months** should be the timeline for all label updates - that is the usual timeline for ATP's when CLH becomes mandatory for specific substances including when the classification of substance(s) is more severe.	

Amendment 2

Proposal for Regulation
Article 30- paragraph 1
Regulation 1272/2008
Article 30 – paragraph 1

Commission Proposal	Proposal for amendment
1. In case of a change regarding the classification and labelling of a substance or a mixture, ~~which results in the addition of a new hazard class or in~~	1. In case of a change regarding the classification and labelling of a substance or a mixture, the supplier shall ensure that the label is updated

~~a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.~~ ~~2.~~ ~~Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1,~~ the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.	within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.
Justification The new CLP Regulation proposal requires labels to be updated within 6 months in case a new hazard class or a more severe classification needs to be assigned to a substance or a mixture, or when new supplemental information on the label is required. This timeline is too short, in particular for complex value chains that involve several mixture formulators downstream, and inconsistent with current practices which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages. Consistent with current rules, we recommend that **18 months** should be the timeline for all label updates - that is the usual timeline for ATP's when CLH becomes mandatory for specific substances including when new classification of substance(s) are more severe.	

Amendment 3
Proposal for Regulation
Article 30- paragraph 2
Regulation 1272/2008
Article 30 – paragraph 2

Commission Proposal	Proposal for amendment
~~2.~~ ~~Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1,~~ the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.	The supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.
Justification The new CLP Regulation proposal requires labels to be updated within 6 months in case a new hazard class or a more severe classification needs to be assigned to a substance or a mixture, or when new supplemental information on the label is required. This timeline is too short, in particular for	

complex value chains that involve several mixture formulators downstream, and inconsistent with current practices which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages. Consistent with current rules, we recommend that **18 months** should be the timeline for all label updates - that is the usual timeline for ATP's when CLH becomes mandatory for specific substances including when new classification of substance(s) are more severe.